

Customer No. 25533

US Patent No. 6,020,329
Attorney Docket No. PC9137C

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE: U. S. PATENT NO. 6,020,329
ISSUED: FEBRUARY 1, 2000
TO: JOHN HARGREAVES BATESON, ET AL.
FOR: CEPHALOSPORINS AND HOMOLOGUES, PREPARATIONS AND
PHARMACEUTICAL COMPOSITIONS
ASSIGNEE: AH USA 42 LLC

Transmittal Letter for Application for Third Interim
Patent Term Extension Under 35 U.S.C. § 156(e)(2)

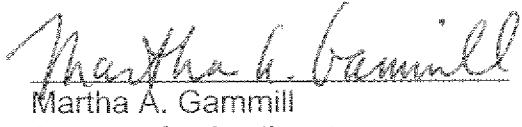
Mail Stop Hatch-Waxman PTE
Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

Dear Sir:

Transmitted herewith is the application of AH USA 42 LLC (formerly Pfizer Inc.), dated April 17, 2013, for a third interim patent term extension of the term of United States Patent No. 6,020,329 under 35 U.S.C. § 156(e)(2), together with a duplicate of the papers thereof, certified as such.

Please charge any fees which may be required by the filing of this application for a third Interim Extension of Patent Term, or credit any overpayment, to Deposit Account No. 50-5996. Two copies of this paper are enclosed.

Dated: 4/17/2013



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**Application for a Third Interim Patent Term
Extension Under 35 U.S.C. § 156(e)(2)**

Mail Stop Hatch-Waxman PTE
Office of Patent Legal Administration
Room MDW 7D55
600 Dulany Street (Madison Building)
Alexandria, VA 22314

Dear Sir:

This paper serves as an application for a third interim patent term extension of U.S. Patent No. 6,020,329 ("the '329 patent") under 35 U.S.C. § 156(e)(2).

AH USA 42 LLC (formerly Pfizer Inc.) (referred to herein as "Applicant") respectfully requests a third interim extension under 35 U.S.C. § 156(e)(2) of the term of the '329 patent for a period of one year from the expiration date of the second interim extension of the '329 patent, which is July 22, 2013, such that the expiration date of the second interim extension of the '329 patent will be extended until July 22, 2014.

On June 22, 2008, Applicant filed an Application for Extension of Patent Term under 35 U.S.C. § 156 for the '329 patent, based on the regulatory approval of CONVENIA® (cefovecin sodium) on April 25, 2008. Applicant has requested extension of the term of the '329 patent from July 22, 2011, to July 23, 2015.

On August 7, 2008, the USPTO sent an initial letter to the Food and Drug Administration (“FDA”), indicating the PTO’s view that the ‘329 would be eligible for extension of the patent term under 35 U.S.C. § 156.

On September 2, 2009, the FDA responded to the PTO confirming CONVENIA® was subject to a regulatory review as the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

On November 25, 2009, the PTO sent a second letter to the FDA requesting FDA’s determination with respect to the applicable regulatory review period.

Since then, to Applicant’s knowledge, there has been no official communications between the two agencies.

On March 2, 2011, Applicant requested an interim patent term extension under 35 U.S.C. § 156(e)(2). The request was granted by the USPTO on July 18, 2011, which extended the term of the “329 patent for a period of one year from the original expiration date of the ‘329 patent to July 22, 2012.

On April 29, 2011, the Federal Register, Vol. 76, No. 83, published a Notice regarding “Determination of Regulatory Review Period for Purposes of Patent Extension; CONVENIA.”

On June 27, 2011, Applicant filed a petition with the FDA requesting revision of the regulatory review period determination for Convenia under 21 CFR § 60.24.

On April 13, 2012, Applicant requested a second interim patent term extension under 35 U.S.C. § 156(e)(2). The request was granted by the USPTO on July 3, 2012, which extended the term of the “329 patent for a period of one year from the extended expiration date of the ‘329 patent to July 22, 2013.

On June 1, 2012, Applicant received FDA’s communication regarding Applicant’s petition dated June 27, 2011. The FDA affirmed the determination of the regulatory review period as published in the Federal Register on April 29, 2011, and denied Applicant’s petition.

Under 37 C.F.R. §1.760, an application for an interim patent term extension under 35 U.S.C. § 156(e)(2) should be filed at least three months prior to the expiration date of the patent. The '329 patent was extended to July 22, 2013, which makes this application for an interim patent term extension timely within the meaning of 37 C.F.R. § 1.760.

In view of the approaching expiration date of the '329 patent, Applicant respectfully requests that an interim extension to July 22, 2014, of the '329 patent under 35 U.S.C. § 156(e)(2) be granted well before July 22, 2013.

Respectfully submitted,

Dated: 4/17/2013


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